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The Role of Quality Assurance in the U.S. Environmental Protection Agency's Air and Energy Engineering Research Laboratory

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Quality Assurance	Stationary Sources	13H, 14D
Quality Control	Data Collection	
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ABSTRACT

Quality assurance (QA) has a major role in the environmental engineering research programs conducted by EPA's Air and Energy Engineering Research Laboratory (AEERL) in Research Triangle Park, North Carolina. Consistent with Agency policy, AEERL requires that all data collection activities be documented by approved QA Project Plans, which establish the data quality needed for a project. AEERL has developed an innovative Project Category approach to QA plan documentation which bases the mandatory reporting elements on the type of research project and the intended use of the data (e.g., rulemaking, fundamental research). This approach is also applied to audits, which ensure that QA requirements are implemented properly. Since 1983, this QA approach has been successfully applied to more than 250 research projects. The adequacy of the quality control documentation is determined through QA review of all related technical reports.

AEERL has implemented a comprehensive QA program based on detailed QA Project Plans, QA audits, and final report reviews which can be readily adapted to other environmentally related, data collection activities at the Federal, State, and local levels.

EVOLUTION OF QUALITY ASSURANCE IN AEERL

The Air and Energy Engineering Research Laboratory (AEERL), Research Triangle Park, NC, has recognized the importance of quality assurance (QA) to environmental measurement activities for more than 10 years. Its importance was recognized formally in 1974 with the publication of the "Planning Document for an IERL* Quality Assurance Program." [1] Subsequently, a data quality program was instituted through the development of QA procedures and their trial implementation on AEERL projects.

In May 1979, the EPA initiated an Agency-wide QA program. This program was designed to ensure that all environmental measurements conducted by EPA regional offices, program offices, laboratories, contractors, grantees, or other EPA-related sources resulted in scientifically valid and defensible data.

In April 1984, EPA Order 5360.1, "Policy and Program Requirements to Implement the Mandatory Quality Assurance Program,"[2] was issued and, for the first time, provided a regulation basis for the QA program in the Agency. The Order specifies certain activities which are considered to be basic to the implementation of a QA program. These activities include:

- Developing QA Project Plans for all projects and tasks involving environmentally related measurements and data collection activities in accordance with approved guidelines.

- Conducting scheduled audits (technical system, performance evaluation, data quality, etc.) of organizational units and projects involving environmentally related measurements.

- Developing and adopting technical guidelines for estimating data quality in terms of precision (variability), bias (accuracy), representativeness, completeness, and comparability, as appropriate, and incorporating data quality requirements in all projects and tasks involving environmentally related measurements.

- Implementing corrective actions, based on audit results, and incorporating this process into accountability systems.

The term "environmentally related measurements" is defined as:

Essentially all field and laboratory investigations that generate data involving: (1) measurement of chemical, physical, or biological parameters in the environment; (2) determination of the presence or absence of specific pollutants in process or waste streams; (3) performance of engineering and process evaluations; (4) study of laboratory simulation of environmental events and process engineering phenomena; and (5) development and validation of any technique, method, or procedure for measuring process and environmental data.

PURPOSE OF THE AEERL QA PROGRAM

The purpose of the Laboratory QA program is to ensure that the R&D activi-

* AEERL is the former Industrial Environmental Research Laboratory.

ties sponsored by AEERL produce results that are of known data quality and are of adequate quality for the technical decision to be made. Data may be good or bad; however, decision-makers must be able to recognize the difference. The QA program is a mechanism to indicate to the data user that the technical objectives have been credibly satisfied.

COMPONENTS OF THE AEERL QA PROGRAM

This paper will address the following key QA program elements: QA Project Plans, QA audits, standard operating procedures, and final report reviews. These elements, when implemented properly, provide adequate documentation of the research program. As noted previously, proper QA will not guarantee error-free data, but it will enable the user to assess the magnitude and implications of the errors.

In examining the elements of the QA program, it is important to first establish the difference between QA and quality control (QC). QA is a management function whose purpose is to establish, implement, and evaluate QC activities and procedures. QC is the routine collection, analysis, and documentation of data for the specific purpose of evaluating and assessing the uncertainties associated with a given measurement method or procedure, and the application of appropriate corrective action.

The discussions that follow address both the QA and QC aspects of project activities. Clearly, the initial step in the process is to determine whether or not QA requirements are applicable to a particular project; that is, does the project involve environmentally related measurements as defined earlier? If so, Agency regulations require that QA-related specifications be incorporated into the procurement or acquisition process to ensure that the offerors meet minimum QA/QC experience levels. When the procurement process has been completed and the contract or financial assistance agreement is in place, the researcher is required to prepare and submit a Quality Assurance Project Plan (QAPP). The QAPP is the cornerstone of the environmental QA program inasmuch as it sets forth the data quality needs of the project and establishes the basis for all QA/QC activities.

PROJECT CATEGORY APPROACH TO QA AND QA PROJECT PLANS

It has been the key objective of the Agency's QA program to ensure that all data collection or measurement activities yield data of known quality and adequate quality for the intended use of the data. The key to achieving this objective is the successful implementation of QAPPs for all such activities. Since 1980, the protocol for QAPPs has been given by QAMS-005/80, "Guidelines for Preparing and Submitting Quality Assurance Project Plans."[3] All QAPPs implemented by contractors under the AEERL QA program through 1984 have followed the QAMS-005/80 guidance, as have QAPPs throughout the Agency.

Experience has shown, however, that the QAMS-005/80 protocol may not be appropriate for all types of work. While QAMS-005/80 has been shown to be applicable to routine data collection activities (e.g., measurements involving

the repeated use of standard or reference methods), this has not been the case for many of the non-routine activities conducted in an R&D program. The detailed specifications of QAMS-005/80 have frequently been too restrictive for many R&D projects, where the use of non-routine measurement methods are the rule rather than the exception. QAMS-005/80 specifies that the project data quality be indicated by precision, accuracy, completeness, representativeness, and reproducibility; however, in many R&D projects, some of these concepts may be neither practical nor achievable. For example, the analysis of a hazardous air pollution sample may involve chemical compounds for which no reference method exists or for which standard materials may not be available or may not exist. In such a situation, the classical concepts of precision and accuracy (bias) are meaningless. Moreover, the rigid documentation requirements of QAMS-005/80 are often too burdensome for the project or task to be performed, particularly when limited resources are available. Clearly, there is little to be gained by having excessive QA/QC requirements consume most of the resources available for a project.

In response to this need, the AEERL has developed an innovative approach to QAPP requirements that is based on the type of work being done and the intended use of the data. AEERL projects are assigned to one of four Project Categories. Each Category specifies a level of QA/QC requirements commensurate with the complexity of the project, the user (or client) for whom the work is being done, etc. Categories are:

- Category I: Rulemaking/Enforcement Support
- Category II: Technology/Strategy Development
- Category III: Applied R&D
- Category IV: Basic R&D/Proof of Concept

The discussions that follow will address the attributes of R&D projects assigned to each Category. As will be shown later, the implications of audits will also depend on the Project Category.

Category I -- Rulemaking/Enforcement Support

Category I projects produce results that are used directly by a client of the Laboratory (e.g., Program Office, Region, or State) for rulemaking, enforcement, legal, or policy matters. Such projects are of critical importance to Agency objectives and may be required to withstand legal challenge. Accordingly, the QA requirements will be the most rigorous and detailed in order to ensure that such objectives are met.

Other projects that could be included in Category I are "high visibility" projects as determined by Laboratory management. Such projects may include tasks which directly support key organization objectives, and whose results may be used to determine policy. In these situations, detailed QA documentation is required to ensure that the data are of sufficient quality to support the policy decisions to be made. These key elements are described in Table I.

Table I. Category I: Key Elements.

1.	Project description, including intended use of the data.
2.	Project organization and project QA/QC organization and responsibilities.
3.	Data Quality Objectives for critical measurements, in terms of precision, accuracy, completeness, representativeness, and comparability, or qualitative acceptance criteria when quantification is not practical.
4.	Site selection and sampling procedures.
5.	Sample custody.
6.	Calibration procedures and frequency.
7.	Analytical procedures.
8.	Data reduction, validation, and reporting, including handling of invalid/missing data.
9.	Internal QC checks and audits.
10.	Results of performance and systems audits.
11.	Preventive maintenance (including procedures and schedules).
12.	Calculation of Data Quality Indicators; specific procedures and statistical methodology to be used in routinely assessing and evaluating data precision and accuracy (both QC and measured), representativeness, comparability, and completeness of the specific measurement parameters involved.
13.	Corrective action (including criteria and procedures).
14.	QC reports to management.

Category II -- Technology/Strategy Development

Category II projects produce results that are used for technology on strategy development. This Category will cover most R&D activities performed by the Laboratory for other organizations not described by Category I. An example would be a control technology performance study for a Program Office background document. The requirements are given in Table II.

Table II. Category II: Key Elements.

1.	Project description (including organization chart).
2.	Data Quality Objectives for critical measurements.
3.	Sampling procedures for critical measurements (including calibration, chain of custody, and preventive maintenance, as appropriate).
4.	Analytical procedures (including instrument calibrations, internal QC checks, and sample custody, as appropriate).
5.	Data reduction methods.
6.	Calculation of Data Quality Indicators (including statistical evaluation techniques).
7.	Corrective action procedures.
8.	System and performance audits (as applicable).

Category III -- Applied R&D

Category III projects produce results that are used to support the R&D program objectives of the Laboratory; that is, projects whose results are used by Laboratory management to develop new R&D projects that will lead to the achievement of a Laboratory technical objective. For example, a Category III project could include the development of a test method for flame zone temperature measurements. The QA documentation requirements allow greater discretion in the contents and format of the QAPP. The QAPP elements are given in Table III.

Table III. Category III: Key Elements.

1.	Project description.
2.	Data Quality Objectives for critical measurements.
3.	Sampling procedures for critical measurements.
4.	Analytical procedures.
5.	Data reduction methods.

(Continued)

Table III. Category III: Key Elements. (Continued)

6. Corrective action procedures.

7. Systems and performance audits (as applicable).

Category IV -- Basic R&D/Proof of Concept

Category IV projects may be described as feasibility studies, "go/no-go" studies, or fundamental/basic research. The QA requirements are generally acceptance criteria, and the originator has wide latitude in defining the contents of the QAPP. Category IV projects would include screening studies to determine the feasibility of using new sorbent materials in the Limestone Injection Multistage Burner (LIMB) program. The contents of a Category IV QAPP are described in Table IV.

Table IV. Category IV: Key Elements.

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1. Project description.

2. Data Quality Objectives/acceptance criteria.

3. Approach to QA/QC.

4. Intended use of the data.

QA PROJECT PLAN REVIEW PROCEDURES

All AEERL technical projects involving environmentally related measurements performed in-house or funded through contracts, cooperative agreements, or interagency agreements require an approved Quality Assurance Project Plan (QAPP).

The QAPP is submitted to the project officer in accordance with a schedule set by the project officer. The project officer will ensure that the QAPP is submitted for QA review at least 30 days prior to the start of measurements to allow the review to be completed without impacting the measurements schedule.

The originator of the QAPP will submit copies of the QAPP to the project officer who, in turn, will provide copies to the Quality Assurance Officer (QAO) for review. The project officer will also provide to the QAO any supporting documentation, such as work plans and standard operating procedures. The QAO and/or designated representative(s) will review the QA Project Plan and prepare written comments, evaluations, and recommendations. Upon completion of review, the QAO will send a cover memorandum with the written comments to the project officer. In the memorandum, the QAO will inform the project officer of the review rating assigned to the QAPP and provide any recommendations for correction. Adjective descriptors, as identified in Table V, will be the standard ratings used. If the rating is either "approved" or "approved with recommendations," no further work on the QAPP will be required unless a major change to the project scope requires the QAPP to be revised.

Table V. QA Project Plan Evaluation Scores.

Adjective Descriptor	Explanation/Corrective Action Required by the Project Officer	Status of Project
Acceptable	None.	Work proceeds
Acceptable with Recommendations	Minimum criteria are met; project officer may implement recommendations to further improve data quality.	Work proceeds
Conditionally Acceptable	Corrections/revisions to the QAPP are required, but the plan is not sufficiently deficient to stop or delay the work.	Work proceeds
Not Approved -- Revisions Required	The QAPP is found sufficiently lacking so that modification of the QAPP is needed before work can proceed.	Measurements may not proceed pending QAPP approval*
Not Approved -- Major Revisions Required	The QAPP has major deficiencies and will require substantial modification or rewriting and resubmittal for review.	Measurements may not proceed pending QAPP approval*

* For Categories I and II: Work may not proceed pending QAPP approval.

A "not approved -- conditionally acceptable" QAPP allows for work to proceed as planned, but does not provide approval of the QAPP. The revised QAPP must respond to review comments and satisfy reviewer questions before it can be approved. Usually, this is accomplished in a memorandum which is appended to the QAPP.

The other "not approved" ratings require that a revised QAPP be submitted and that work may not usually proceed until the revised QAPP has one of the adjective descriptors. No measurements work may proceed for Category I or II projects without an approved QAPP.

For Category III projects, work may continue with the Branch Chief's written approval while revisions are made to the QAPP. If the deficiencies are not resolved within 60 days from the date of the QAO's memo on the QAPP to the project officer, then all measurements work will stop. Category IV projects do not require QAO approval.

As noted above, revisions are required when a plan is found unacceptable or when the scope of work is modified. All substantive revisions of approved QAPPs require review and approval using the same procedures as required for the original QAPP. It is the responsibility of the project officer to ensure that QAPP revisions are received in a timely manner and that any project delays resulting from the unacceptable QAPP are minimized. When the revisions are received, they are reviewed and scored in the same manner as the original.

QUALITY ASSURANCE AUDITS

Audits are used to determine compliance with the approved QAPPs and to assess the overall quality of data collected during the measurements program. Additionally, audits are useful in evaluating procedures used in collecting and analyzing samples, in all facets of data handling, and in management of the program. Often an audit of a measurements program will detect programs which may otherwise have gone undetected until the end of testing. In these situations, the audit may not only minimize the collection of invalid data, but also result in savings of time and costs associated with retesting.

AEERL audit activities can be broken down into four types of audits: the Management Systems Audit (MSA), Technical Systems Audit (TSA), Performance Evaluation Audit (PEA), and Audit of Data Quality (ADQ). The following sections discuss these audits in detail, as well as procedures for selecting audit subjects, evaluation criteria, and audit reporting.

Management Systems Audits

A Management Systems Audit (MSA) is a qualitative on-site audit of an organization's QA management system. The audit is used to verify the existence and evaluate the adequacy of the internal management systems necessary for the successful implementation of a QA program. The primary purpose of an MSA is to determine the extent to which QA has been institutionalized within an organization and to recommend actions to correct deficiencies found.

Management Systems Audits are designed to answer the following questions:

- Does the management policy of the organization identify the specific role of QA in its operations?
- Does the organization maintain official position descriptions for all QA personnel and provide for a QA program that includes appropriate milestones and documentation of specific, individual work assignments?
- Is it possible to identify specific resources that were allocated to the management of the organization's QA program?
- For projects involving environmental measurements, does the QA officer maintain an adequate system for determining the status of documents or activities required of individual projects?
- Is there adequate training in QA, and is there evidence of a routine concern in organizational activities?

Generally, the MSA covers all QA aspects of the organization's policies, personnel management, project management, resources, training, and scheduling. Problems identified in these areas are documented in an audit report to the EPA QAO and project officer.

Technical Systems Audits

A Technical Systems Audit (TSA) is a qualitative on-site evaluation of a measurement system. The objective of the TSA is to assess and document all facilities, equipment, systems, recordkeeping, data validation, operation, maintenance, calibration procedures, reporting requirements, and QC procedures. Because the above items should be defined in the approved Quality Assurance Project Plan (QAPP) for the project under evaluation, the QAPP provides the basis for the audit. During the audit, any undocumented or unauthorized deviations from the QAPP are cited and noted in the audit report.

While the TSA does not provide any quantitative information, the information collected during the audit helps the auditor quickly determine whether the quality of data is likely to be adequate for the intended use of the data, or whether problems present during the test may lead to erroneous results. Suspicions regarding data quality may be confirmed later using the results of a PEA.

Performance Evaluation Audits

A Performance Evaluation Audit (PEA) is a quantitative evaluation of a measurement system. Although it is possible for each measurement of a test program to be subjected to a PEA, it is more common for only the critical or most important measurements to be evaluated, as designated in the approved (QAPP). The performance evaluation of a measurement system usually involves the measurement or analysis of a reference material, having associated with it a known value or composition. It is important that the value or composition of the reference material be certified, or at least verified, prior to use, and

that the certification or verification be adequately documented. Usually the identity of the reference material will be disguised so that the operator or analyst will treat it no differently from a test program sample.

A valid PEA will provide answers to the following questions:

- What are the accuracy and precision of the measurement system at the time of the audit?
- Do the QC data collected during routine system operations correctly reflect data quality?
- Is the measurement system operating within the established statistical control limits?
- If the results of previous audits are available, has data quality significantly changed?

Although the answers to these questions will help determine when a system is out of control, the appropriate corrective action may not always be evident. In these cases, a Technical Systems Audit may be required.

Audits of Data Quality

An Audit of Data Quality (ADQ) involves assessments of the methods used to collect, interpret, and report the information required to characterize data quality. The assessment of these data quality indicators requires a detailed review of: (1) the recording and transfer of raw data; (2) data calculations; (3) the documentation of procedures; and (4) the selection and discussion of appropriate data quality indicators.

Collection of sufficient information to answer the following questions is within the scope of ADQs:

- Is there sufficient documentation of all procedures used in the data collection effort to allow for repetition of the effort by a person or team with technical qualifications similar to those of the original data collector?
- Is there sufficient documentation to verify that the procedures specified for use in the data collection effort were properly followed?
- Is sufficient information presented to enable potential users to evaluate the limitations of the data and to determine whether the intended use of the data is appropriate?

The results of an ADQ are used to determine whether the data collection efforts need modification, and whether the use and documentation of QC procedures are adequate.

SELECTION OF AUDIT SUBJECTS

Within AEERL, the decision to audit a project and the selection of the type of audit to be performed is made by the project officer, the QAO, or the Laboratory Director. In selecting projects to audit, the following criteria are considered:

- o Direct Program Office Support (Category I)
- o High Visibility Projects (as determined by the Laboratory Director)
- o Project/task officer request
- o QAO selection

The last criterion (i.e., QAO selection) is to allow for a completely independent audit of Laboratory projects that do not fit into the other categories. For example, a new or previously unaudited contractor may be selected for an audit to enable the Laboratory to gain a better understanding of the contractor's capabilities. Frequently, QAO-selected audits are follow-ups to earlier audits to determine if previously cited deficiencies have been corrected.

AUDIT PROCEDURES

Once the decision to audit a project is made, it is the QAO's responsibility to notify all involved personnel and to assemble an audit team. The audit team may include personnel from a QA support contractor who has been designated as the QAO's representative. The organization to be audited is usually notified in advance so that preparations for the audit can be made. Unannounced audits are performed only under extraordinary circumstances.

Prior to the audit, the audit team thoroughly reviews all applicable and available documentation, including work plans, QAPPs, test plans, and all sampling and analytical protocols. Audit checklists are prepared, and an audit agenda is defined. The audit agenda includes the following items or activities:

- o Pre-audit, on-site, meeting with test personnel.
- o Audit activities.
- o Post-audit discussion with test personnel.

The purpose of the pre-audit meeting is to introduce audit team members to the organization personnel, to explain the audit activities to be performed, and to coordinate these activities with the organization's schedule. The post-audit discussion allows the auditors to ask any final questions and to present verbally the preliminary findings of the audit.

Audit team members are instructed not to interfere with the activities of the group being audited. At the same time, the group being audited is expected to accommodate the needs of the auditor to the greatest extent possible without disrupting the data collection activities. For example, the auditors may need to

ask questions concerning procedures, review records and laboratory books, and observe the activities of sampling or laboratory personnel. The audit team usually performs its duties while the testing is in progress and during scheduled breaks. Although occasionally the group being audited may need to make special arrangements (e.g., assigning extra personnel or lengthening the test day), such adjustments should be minimized.

EVALUATION AND CORRECTIVE ACTION

After completion of the audit, the audit team assigns an evaluation rating to the group that was audited. The ratings and the corrective actions required of the project officer are presented in Table VI. In cases where the rating is unacceptable, the QAO and audit team leader meet with the project officer as soon after the audit as possible to discuss the preliminary findings. Unless the unacceptable aspects of the test program are resolved promptly, it may be necessary for the QAO to recommend to Laboratory management that work be suspended.

If a problem discovered during the audit is sufficiently serious to warrant an unacceptable rating, the audit team will issue a Corrective Action Recommendation (CAR). The serious problem(s) is described in the CAR and copies are forwarded to the project officer, his immediate supervisor, the group that was audited, and the QAO. The project officer receiving the CAR is then briefed by the QAO on the immediate findings of the audit and later receives from the QAO a memorandum or report discussing the audit findings in detail. The project officer's responsibility is to: (1) resolve any deficiencies sited in the CAR, and (2) document any corrective actions taken and their anticipated effect. While there is no specific time-frame for resolving CAR issues, they should be resolved promptly, especially where suspension of work has been recommended. In most cases, the auditee's response to CAR issues has been prompt and acceptable.

If the project officer objects to the audit evaluation and the issues cannot be resolved through discussions with the QAO, the matter will be brought to the attention of the Laboratory senior management for resolution. The Laboratory Director will have the final decision in any arbitration. Such arbitration has been needed infrequently.

Table VI. AEERL Audit Rating System.

Adjective Descriptor	Explanation/Corrective Action Required by Project Officer	Status of Measurements
Acceptable	None	Work proceeds
Acceptable with Qualifications	Minimum criteria are satisfied and good data quality seems likely; qualifications on the possible limitations of the data are noted and some corrective actions may be recommended. The recommendations may be implemented at the project officer's discretion.	Work proceeds

(Continued)

Table VI. AEERL Audit Rating System. (Continued)

Conditionally Acceptable	Some corrective actions are required by the project officer to ensure quality results, but the deficiencies are not so serious as to halt work.	Work proceeds
Not Acceptable -- Corrective Actions Required	The audit reveals deficiencies that require the project officer to take corrective action before work can proceed.	Measurement work may stop until deficiencies are resolved.
Not Acceptable -- Major Corrective Actions Required	Major deficiencies are revealed by the audit that require the project officer to take substantial corrective action before measurements work can proceed.	Measurement work mayl stop until deficiencies are resolved.

The resolution of any audit issues is documented by the QAO to the project officer and his management. In situations deemed appropriate, other Laboratory or Agency personnel may be apprised of audit results. These situations include the determination of serious deficiencies that may adversely affect other Laboratory or Agency programs, and the apprisals are done with the concurrence of the project officer involved.

The QAO has the authority to recommend the temporary suspension of any on-going technical project activity on the basis of: (1) audit results; (2) project officer request; or (3) other justifiable circumstances. The suspension of activities continues until the appropriate corrective action is initiated. The responsibility for corrective action in such cases is shared by the QAO, the project officer, the principal investigator, and managers up through the Laboratory Director.

REPORTING OF AUDIT RESULTS

The audit team reports verbally, or by means of a preliminary report, to the QAO immediately upon return from the audit. If immediate corrective action is recommended, the QAO will contact the project officer to discuss possible actions. Within 30 days, the audit team provides a formal written draft audit report to the QAO. At that time, a memorandum of findings that includes an "adjective descriptor" from Table VI is sent from the QAO to the project officer. A draft copy of the audit report is included with the memorandum. Sometimes it is necessary to delay the release of the audit report beyond 30 days. This situation may occur whenever the audit team must wait for supplemental data to be provided by the audited organization. The draft audit report is provided to the project officer for his review and that of the audited organization to determine if any "factual errors" have occurred; that is, if anything was stated in the

report that was erroneous or that inaccurately described a situation. If so, corrections will be made and a final audit report will be issued. If there has been no response to the audit report after 30 days of its issue, the report is assumed to be correct and the final audit report is issued.

QUALITY CONTROL EVALUATION REPORT

Data quality reporting is the key to success in a QA program. This is the final documentation of data quality activities. It should be sufficiently detailed to convey a clear understanding of the data quality to the user.

Each interim or final report produced by a measurements or data generation activity for which a QAPP was required must include as an integral section of the project report, or as an appendix, a readily identifiable discussion of the data quality of the research results. This discussion is called the Quality Control Evaluation Report (QCER).

Because the nature of Laboratory R&D activities varies widely, the format of the QCER and, to a large degree, its contents, are left to the discretion of the project officer. As a minimum, the QCER must contain:

- Discussions of the quality of data produced in terms of precision, accuracy, completeness, representativeness, and comparability, or semi-quantitative assessments of data quality, as applicable.
- Limitations or constraints on the use or applicability of the data, if any.
- Results of systems or performance audits.
- Identification of any significant QA/QC problems encountered (i.e., resolution of corrective actions).

In general, the QCER discussion should reflect the Project Category. The purpose of the QCER is to substantiate and document the data quality achieved in the research activity. If the technical objectives were met and the data were of adequate quality, then the QCER provides sufficient information to enable the user of the technical results to have confidence in using the data. For example, a good QCER will relate the achieved data quality to the original data quality objectives stated at the outset of the activity and will explain any significant differences. It is also important that any limitations on the use of the data be stated by those who generated the actual data. The results of any audits should also be discussed. This applies to internal audits as well as to any conducted by EPA. Audit results may provide useful information to the data user regarding measurement or analytical systems that may give additional insight to the ultimate utility of the technical results. For example, audit results reported in a QCER could show that a particular measurement technique was unreliable in a specific situation not encountered before or that the data user may plan to utilize. It is also important to document that, when audits discovered problems, the problems were corrected. This documentation strengthens the credibility of the technical data.

The QA officer will review the report to determine that the QCER is included and adequately documents the quality of the data reported. If deficiencies are indicated, it is the project officer's responsibility to have the deficiencies corrected and to resubmit the report for verification.

SUMMARY

The AEERL QA program has been successfully applied to more than 250 research projects during the past 3 years. The sequence of activities is well-defined and understood by the technical managers and staff, and has been documented in two QA procedures manuals, one for Laboratory project officers and one for contractors and financial assistance recipients who conduct research for the Laboratory. During this same period, the structured protocol offered by the Laboratory QA program has resulted in significant improvements in the "quality" of the QA documentation. That is, few QAPPs are found to be unacceptable; few reports require revision to include QA/QC documentation. The audits protocol has shown that fewer projects have serious problems, which is due largely to the planning and increased awareness of QC that now typifies the majority of the Laboratory's research efforts.

It must be conceded, however, that QA exacts a price. The costs associated with implementing a comprehensive QA/QC program may be large, but these costs have been recovered many times over in terms of improved data quality (which has led to more effective decision-making) and by providing legally defensible data.

REFERENCES

1. U.S. Environmental Protection Agency, Planning Document for an IERL Quality Assurance Program, 1974.

2. U.S. Environmental Protection Agency Order 5360.1, "Policy and Program Requirements to Implement the Mandatory Quality Assurance Program," April 1984.

3. Quality Assurance Management Staff, "Guidelines for Preparing and Submitting Quality Assurance Project Plans," QAMS-005/80, December 1980.